

Notice of Allowability

Application No.

10/790,549

Applicant(s)

HICKEY ET AL.

Examiner

Janet L. Coppins

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' Amendment of September 26, 2007.
2. ☒ The allowed claim(s) is/are 1-10.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date ____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____ |

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DETAILED ACTION

1. Claims 1-10 are pending in the instant application.

Response to Amendment

2. Applicants' Amendment and Response of September 26, 2007, has been reviewed by the Examiner and entered in the file. Accordingly, amendments to claims 1, 2, 4, 7, 9 and 10 have been entered.

Double Patenting

3. Claims 1-9 previously rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,420,364 B1 to Emmanuel et al.
4. In response to the obviousness-type double patenting rejection, Applicants have submitted a Declaration presenting evidence of unexpected results of the instant compounds over the compounds of the closest prior art. Accordingly, the Declaration under 37 CFR 1.132 filed September 26, 2007 is sufficient to overcome the rejection of claims 1-9 based upon unexpected results, including improved selectivity for cathepsin S.
5. Claims 1-9 now appear to be allowable over the prior art. Therefore, claim 10, drawn to methods of treatment, is herein rejoined for examination on the merits.

REASONS FOR ALLOWANCE

6. In view of Applicant's amendatory changes and cancellations, claims 1-3, 5-7, 12-15, 22, 24-30, 32, and 34 are allowable over the prior art, as newly renumbered claims 1-20. The following is an examiner's statement of reasons for allowance:

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This invention relates to novel morpholine-4-carboxylic acid-(4-cyano-1-methyl-4-carbamoyl-piperidine)-amide derivatives and their methods of use. The allowable compounds are limited to compounds according to formulae (I) or (II) of claim 1. Certain peptidyl compounds are known in the art as having the ability to inhibit cathepsin activity, however the aspect of preparing the instant claimed morpholine-4-carboxylic acid-(4-cyano-1-methyl-4-carbamoyl-piperidine)-amide derivatives, with cathepsin S inhibitory activity, is novel and unobvious. The instant compounds were tested for selective inhibition of cathepsin S over Cathepsin L (please refer to unexpected inhibitory results found in the table on pages 3-4 of the declaration), which makes them useful as immunomodulatory agents. After a thorough search, the closest of prior art, U.S. Pat. No. 6,525,052 to Bakkali et al. was found to teach similar peptidyl derivatives that are useful as cysteine protease inhibitors. However the '052 patent fails to teach or render obvious the instant claimed compounds according to formulae (I) or (II), and does not fairly suggest methods of using the instant claimed compounds as cathepsin S inhibitors.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

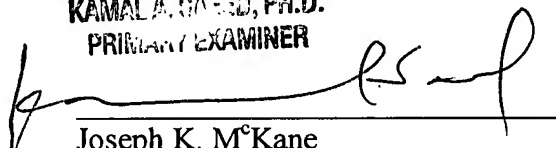
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
September 30, 2007

KAMALA A. GAZD, PH.D.
PRIMARY EXAMINER



Joseph K. McKane
SPE, Art Unit 1626